DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 5, 2015

Galil Medical Incorporated
Ms. Amy McKinney
Vice President, Global Regulatory Affairs & Quality
6518 Tamarind Sky Lane
Fulshear, Texas 77441

Re: K143564
Trade/Device Name: Visual-ICE® Cryoablation System, Software Revision 1.3.1
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: Class II
Product Code: GEH
Dated: February10, 2015
Received: February 11, 2015

Dear Ms. McKinney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143564

Device Name
Visual-ICE Cryoablation System, Software Revision 1.3.1

Indications for Use *(Describe)*
The Visual-ICE Cryoablation System is indicated for use as a cryosurgical tool in the fields of general surgery, dermatology, neurology (including cryoanalgesia), thoracic surgery, ENT, gynecology, oncology, proctology, and urology. This system is designed to destroy tissue (including prostate and kidney tissue, liver metastases, tumors, skin lesions) by the application of extremely cold temperatures. The Visual-ICE Cryoablation System has the following specific indications:

- Urology: Ablation of prostate tissue in cases of prostate cancer and Benign Prostate Hyperplasia (BPH)
- Oncology: Ablation of cancerous or malignant tissue and benign tumors, and palliative intervention
- Dermatology: Ablation or freezing of skin cancers and other cutaneous disorders, destruction of warts or lesions, angiomas, sebaceous hyperplasia, basal cell tumors of the eyelid or canthus area, ulcerated basal cell tumors, dermatofibromas, small hemangiomas, mucocele cysts, multiple warts, plantar warts, actinic and seborrheic keratosis, cavernous hemangiomas, peri-anal condylomata, and palliation of tumors of the skin
- Gynecology: Ablation of malignant neoplasia or benign dysplasia of the female genitalia
- General surgery: Palliation of tumors of the rectum, hemorrhoids, anal fissures, pilonidal cysts, and recurrent cancerous lesions, ablation of breast fibroadenomas
- ENT: Palliation of tumors of the oral cavity and ablation of leukoplakia of the mouth
- Thoracic surgery: Ablation of arrhythmic cardiac tissue cancerous lesions
- Proctology: Ablation of benign or malignant growths of the anus or rectum, and hemorrhoids

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Section 5. 510(k) Summary

510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

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Device Name: Visual-ICE® Cryoablation System, Software Revision 1.3.1
IceRod 1.5 CX Cryoablation Needle

Device Classification Name: Cryosurgical unit and accessories (GEH)
21 CFR 878.4350

Predicate Device: Visual-ICE® Cryoablation System (K113860)
Visual-ICE® Cryoablation System, Software Revision 1.2.2 (K123865)
IceRod CX Cryoablation Needle (K121251)

Date of Preparation: March 3, 2015

Device Description:

The Visual-ICE Cryoablation System is a mobile console system intended for cryoablative tissue destruction using a minimally invasive procedure. The system is computer-controlled with a touch screen user interface that allows the user to control and monitor the procedure. The therapy delivered by the system is based on the Joule-Thomson effect displayed by compressed gases. The Visual-ICE System uses high-pressure argon gas that circulates through closed-tip cryoablation needles to induce tissue freezing. Active tissue thawing is achieved by circulating helium gas through the needles or, alternatively, by the use of Galil Medical i-Thaw® technology in which a heating element inside the cryoablation needle can be

energized to cause thawing.

This Special 510(k) is being submitted to modify the software with a variety of changes to enhance usability of the system. The functions of the system that users use to deliver the cryoablation treatment remain unchanged. The table below provides a summary comparison of the changes included in this Special 510(k).

User Interface Changes	• Added information to be displayed on Big Timers and made timers movable • Modified wording on all displayed messages for clarity • Minor appearance modifications • Minor bug fixes
Service and Maintenance Changes	• Minor updates used only by service personnel
Functional Changes	• Modified wording for clarity. • Removed lockout for procedure at maintenance due and end of life; will display warning upon startup. • Allow for user configurable time parameter for displayed low gas message. • Removed restriction for programming up to three freeze thaw cycles. • Added ability to load and save pre-programmed freeze-thaw cycles. • Allow cautery and freeze in any order. • Added a 30 second flush after a freeze. • Added ability to display internal gas temperature of i-Thaw capable needles. • Added gas line flush at start of every procedure • Minor bug fixes

Intended Use:

The Visual-ICE Cryoablation System is indicated for use as a cryosurgical tool in the fields of general surgery, dermatology, neurology (including cryoanalgesia), thoracic surgery, ENT, gynecology, oncology, proctology, and urology. This system is designed to destroy tissue (including prostate and kidney tissue, liver metastases, tumors, skin lesions) by the application of extremely cold temperatures. The Visual-ICE Cryoablation System has the following specific indications:

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• **Dermatology**	Ablation or freezing of skin cancers and other cutaneous disorders Destruction of warts or lesions, angiomas, sebaceous hyperplasia, basal cell tumors of the eyelid or canthus area, ulcerated basal cell tumors, dermatofibromas, small hemangiomas, mucocele cysts, multiple warts, plantar warts, actinic and seborrheic keratosis, cavernous hemangiomas, peri-anal condylomata, and palliation of tumors of the skin
• **Gynecology**	Ablation of malignant neoplasia or benign dysplasia of the female genitalia
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• **ENT**	Palliation of tumors of the oral cavity and ablation of leukoplakia of the mouth
• **Thoracic surgery**	Ablation of arrhythmic cardiac tissue cancerous lesions
• **Proctology**	Ablation of benign or malignant growths of the anus or rectum, and hemorrhoids

Summary of Performance Data and Substantial Equivalence:

The Visual-ICE System and software were evaluated in accordance with Galil Medical's risk management plan. No new unacceptable risks were identified based on the changes incorporated into Software Revision 1.3.1. Complete software verification and validation testing was completed on the new software revision. Software Revision 1.3.1 passed all verification and validation testing. No changes were made to the Visual-ICE System hardware.

Conclusion:

The information and data provided in this Special 510(k) establish that the Visual-ICE Cryoablation System Software Revision 1.3.1 is substantially equivalent to the legally marketed predicate device.